

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use PENTETATE ZINC TRISODIUM INJECTION safely and effectively. See full prescribing information for PENTETATE ZINC TRISODIUM INJECTION

Pentetate zinc trisodium injection (Zn-DTPA) for intravenous or inhalation administration

Initial U.S. Approval: 2004

WARNING: ASTHMA EXACERBATION WITH NEBULIZATION and DEPLETION OF TRACE METALS DURING THERAPY

See full prescribing information for complete boxed warning.

- Nebulized Zn-DTPA may be associated with asthma exacerbation. (5.1)
- Zn-DTPA is associated with depletion of trace metals. The risk for depletion increases when Zn-DTPA is administered over several months. Monitor serum zinc levels, serum creatinine, BUN, electrolytes, urinalysis and blood cell counts during Ca-DTPA or Zn-DTPA therapy. (2.4, 5.2)

INDICATIONS AND USAGE

Pentetate zinc trisodium injection is a radiomitigation chelator indicated for treatment of individuals with known or suspected internal contamination with plutonium, americium, or curium to increase the rates of elimination. (1)

DOSAGE AND ADMINISTRATION

Chelation treatment is most effective if administered within the first 24 hours. Administer Ca-DTPA, if available, as the initial dose. (2.1, 2.2)

If Ca-DTPA is not available during the first 24 hours,

- in adults and adolescents, administer intravenously a single 1.0 gram Zn-DTPA initial dose. (2.1)
- in children less than 12 years of age, administer intravenously a single 14 mg/kg Zn-DTPA initial dose, not to exceed 1.0 gram. (2.1)

After the first 24 hours, continue chelation therapy with Zn-DTPA:

- in adults and adolescents, administer intravenously 1.0 gram Zn-DTPA once daily. (2.1)
- in children less than 12 years of age, administer intravenously 14 mg/kg Zn-DTPA once daily, not to exceed 1.0 gram daily. (2.1)

See Full Prescribing Information for dose (2.1) and nebulized chelation therapy. (2.3)

DOSAGE FORMS AND STRENGTHS

1000 mg / 5 mL single-use ampoules. (3)

CONTRAINDICATIONS

None (4)

WARNINGS AND PRECAUTIONS

- Nebulized chelation therapy may be associated with exacerbation of asthma. Monitor patients for signs and symptoms of asthma exacerbation when administering Zn-DTPA by the inhalation route. (5.1)
- Zn-DTPA is associated with depletion of endogenous trace metals (e.g., zinc, magnesium, manganese). (5.2)
- Take appropriate safety measures to minimize contamination of care-takers by contaminated body fluids. (5.3)

ADVERSE REACTIONS

There is limited experience with Zn-DTPA. Nebulized chelation therapy may be associated with exacerbation of asthma. Headache, light-headedness, and pelvic pain have been reported. (6)

To report SUSPECTED ADVERSE REACTIONS, contact the hameln Pharmacovigilance Department at +44 (0) 7706 210 133 or drugsafety@hameln.co.uk or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

Adequate and well-controlled drug-drug interaction studies in humans were not identified in the literature. (7)

USE IN SPECIFIC POPULATIONS

- Nursing Mothers: Women with known or suspected internal contamination with radioccontaminants should not breast feed, whether or not they are receiving chelation therapy. (8.3)
- Pediatric Use: Safety and effectiveness of intravenous Zn-DTPA were extrapolated from adults. Safety and effectiveness of nebulized route of administration have not been established. (8.4)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 3/2013

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FULL PRESCRIBING INFORMATION

WARNING: ASTHMA EXACERBATION WITH NEBULIZATION and DEPLETION OF TRACE METALS DURING THERAPY

- **Nebulized Zn-DTPA may be associated with asthma exacerbation. (5.1)**
- **Zn-DTPA is associated with depletion of trace metals. The risk for depletion increases when Zn-DTPA is administered over several months. Monitor serum zinc levels, serum creatinine, BUN, electrolytes, urinalysis and blood cell counts during Ca-DTPA or Zn-DTPA therapy. (2.4, 5.2)**

1 INDICATIONS AND USAGE

Zn-DTPA is indicated for treatment of individuals with known or suspected internal contamination with plutonium, americium, or curium to increase the rates of elimination.

2 DOSAGE AND ADMINISTRATION

2.1 Dose

Administer Ca-DTPA as the initial dose during the first 24 hours after internal contamination. Ca-DTPA is more effective than Zn-DTPA during this time period (see Ca-DTPA labeling). If Ca-DTPA is not available, use Zn-DTPA as initial therapy. On the next day, if additional chelation therapy is indicated, begin daily treatment with Zn-DTPA. If Zn-DTPA is not available, chelation therapy may continue with Ca-DTPA and concomitant mineral supplements containing zinc should be given (see Ca-DTPA labeling).

Do not administer more than one dose per 24 hour period.

If Ca-DTPA is not available during the first 24 hours:

- in adults and adolescents, administer intravenously a single 1.0 gram initial dose of Zn-DTPA.
- in children less than 12 years of age, administer intravenously a single 14 mg/kg initial dose of Zn-DTPA, not to exceed 1.0 gram.

After the first 24 hours, continue chelation therapy with Zn-DTPA:

- in adults and adolescents, administer intravenously 1.0 gram Zn-DTPA once daily.
- in children less than 12 years of age, administer intravenously 14 mg/kg Zn-DTPA once daily, not to exceed 1.0 gram daily.

Renally Impaired Patients

No dose adjustment is needed. However, renal impairment may reduce the rate at which chelators remove radiocontaminants from the body. In heavily contaminated patients with renal impairment, dialysis may be used to increase the rate of elimination. High efficiency high flux dialysis is recommended. Because dialysis fluid will become radioactive, radiation precautions must be taken to protect personnel, other patients, and the general public.

2.2 General

Chelation treatment is most effective if administered within the first 24 hours after internal contamination. Start chelation treatment as soon as possible after suspected or known internal contamination. When treatment cannot be started right away, give chelation treatment as soon as it becomes available. Chelation treatment is still effective even after time has elapsed following internal contamination. The chelating effects of Zn-DTPA are greatest when the radiocontaminants are still circulating or are in interstitial fluids. The effectiveness of chelation decreases with time following internal contamination as the radiocontaminants become sequestered in liver and bone.

If internal contamination with radiocontaminants other than plutonium, americium, or curium, or unknown radiocontaminants is suspected, additional therapies may be needed (e.g., Prussian blue, potassium iodide).

2.3 Methods of Administration

Use intravenous administration of Zn-DTPA if the route of internal contamination is not known or if multiple routes of internal contamination are likely. Administer Zn-DTPA solution (1 gram in 5 mL) either with a slow intravenous push over a period of 3 – 4 minutes or by intravenous infusion over 30 minutes diluted in 100 - 250 mL of 5% dextrose in water (D5W), Ringers Lactate, or Normal Saline.

In individuals whose internal contamination is only by inhalation, Zn-DTPA can be administered by nebulized inhalation as an alternative route of administration.

Dilute Zn-DTPA for nebulization at a 1:1 ratio with sterile water or saline. After nebulization, encourage patients to avoid swallowing any expectorant. Some individuals may experience respiratory adverse events after inhalation therapy. [See [Warnings and Precautions \(5.1\)](#)] The safety and effectiveness of the nebulized route of administration have not been established in the pediatric population.

The safety and effectiveness of the intramuscular route of injection have not been established.

2.4 Monitoring

When possible, obtain baseline blood and urine samples (CBC with differential, BUN, serum chemistries and electrolytes, urinalysis and blood and urine radioassays) before initiating treatment.

To establish an elimination curve, obtain a quantitative baseline estimate of the total internalized transuranium element(s) and measures of elimination of radioactivity by appropriate whole-body counting, by bioassay (e.g., biodosimetry), or fecal/urine sample whenever possible.

During Treatment

- Measure the radioactivity in blood, urine, and fecal samples weekly to monitor the radioactive contaminant elimination rate.
- Monitor CBC with differential, BUN, serum creatinine and electrolytes, and urinalysis measurements.
- Record any adverse events from Zn-DTPA.

3 DOSAGE FORMS AND STRENGTHS

1000 mg / 5 mL single-use ampoules.

4 CONTRAINDICATIONS

None

5 WARNINGS AND PRECAUTIONS

5.1 Asthma Exacerbation

Nebulized chelation therapy is associated with asthma exacerbation. Monitor patients for signs and symptoms of asthma exacerbation when administering Zn-DTPA by the inhalation route. [See [Adverse Reactions \(6\)](#)]

5.2 Depletion of Body Trace Mineral Stores

Zn-DTPA treatment may lead to depletion of body stores of endogenous metals (e.g. magnesium, manganese). The risk for depletion increases when Zn-DTPA is administered over several months. Monitor serum zinc levels, electrolytes and blood cell counts during Ca-DTPA or Zn-DTPA therapy. Give mineral or vitamin plus mineral supplements as appropriate. [See [Dosage and Administration \(2.4\)](#)]

5.3 Risks to Care-takers

Radioactive metals are known to be excreted in the urine, feces, and breast milk. In individuals with recent internal contamination with plutonium, americium, or curium, Zn-DTPA treatment increases excretion of radioactivity in the urine. Take appropriate safety measures to minimize contamination of others. [See [Patient Counseling Information \(17\)](#)]

6 ADVERSE REACTIONS

In the U.S. Registry, a total of 646 individuals received at least one dose of either Ca-DTPA or Zn-DTPA. Of these, 62 received Zn-DTPA by one or more routes of administration. Forty-eight individuals were dosed by intravenous administration, 18 by inhalation and 8 by other or unknown routes of administration.

Of the individuals that received Zn-DTPA, 23/62 (37%) received one dose and 8 (13%) received two doses. The remaining 31 individuals received three or more doses. The largest number of Zn-DTPA doses to a single individual was 574 doses delivered over 3.5 years.

Overall, the presence or absence of adverse events was recorded in 310/646 individuals. Of these 19 (6.1%) individuals reported at least one adverse event. The total number of recorded adverse events was 20. Of the 20 adverse events, 1 individual treated with Zn-DTPA reported headache, lightheadedness, and pelvic pain.

Two individuals experienced cough and/or wheezing with nebulized Ca-DTPA therapy however there was no report of such events with nebulized Zn-DTPA.

7 DRUG INTERACTIONS

Adequate and well-controlled drug-drug interaction studies in humans were not identified in the literature. When an individual is contaminated with multiple radiocontaminants, or when the radiocontaminants are unknown, additional therapies may be needed (e.g., Prussian blue, potassium iodide).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category B

Risk Summary

There are no adequate and well-controlled studies of Zn-DTPA use in pregnant women. Chelation treatment of pregnant women should begin and continue with Zn-DTPA. Reproduction studies have been performed in pregnant mice at doses up to 31 times (11.5 mmol/kg) the recommended daily human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Zn-DTPA. There was a slight reduction in the average birth weight. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

8.3 Nursing Mothers

It is not known whether Zn-DTPA is excreted in human milk. Radiocontaminants are known to be excreted in breast milk. Women with known or suspected internal contamination with radiocontaminants should not breast feed, whether or not they are receiving chelation therapy. Precautions should be taken when discarding breast milk. [See [Warnings and Precautions \(5.3\)](#)]

8.4 Pediatric Use

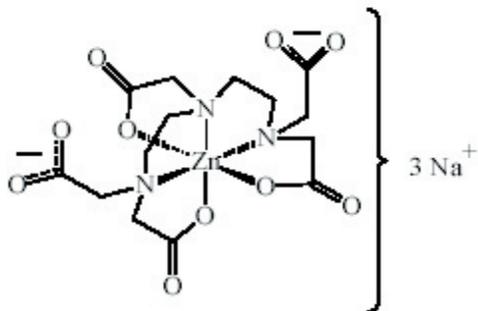
The safety and effectiveness of Zn-DTPA were established in the adult population and efficacy was extrapolated to the pediatric population for the intravenous route based on the comparability of pathophysiologic mechanisms. The dose is based on body size adjustment for an intravenous drug that is renally cleared [See [Dosage and Administration \(2.1\)](#)]. The safety and effectiveness of the nebulized route of administration have not been established in the pediatric population.

10 OVERDOSAGE

Overdose with Zn-DTPA has not been reported.

11 DESCRIPTION

Pentetate zinc trisodium injection contains the sodium salt of zinc diethylenetriaminepentaacetate. Pentetate zinc trisodium is also known as trisodium zinc diethylenetriaminepentaacetate and is commonly referred to as Zn-DTPA. It has a molecular formula of $\text{Na}_3\text{ZnC}_{14}\text{H}_{18}\text{N}_3\text{O}_{10}$ and a molecular weight of 522.7 Daltons. It is represented by the following structural formula:



Zn-DTPA is supplied as a clear, colorless, hyperosmolar (1260 mOsmol/kg) solution in a colorless ampoule containing 5 mL. The ampoule contents are sterile, non-pyrogenic and suitable for intravenous administration. Each mL of solution contains the equivalent of 200 mg pentetate zinc trisodium (obtained from 150.51 mg pentetic acid, 31.14 mg zinc oxide and NaOH) and water for injection, USP. The pH of the solution is adjusted with NaOH and is between 6.5 – 7.5.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Zn-DTPA forms stable chelates with metal ions by exchanging zinc for a metal of greater binding capacity. The radioactive chelates are then excreted by glomerular filtration into the urine. In animal studies, Zn-DTPA forms less stable chelates with uranium and neptunium in vivo resulting in deposition of these elements in tissues including the bone. Zn-DTPA treatments are not expected to be effective for uranium and neptunium. Radioactive iodine is not bound by DTPA.

12.2 Pharmacodynamics

In a study of rodents internally contaminated with plutonium, the rate of plutonium elimination was measured after treatment with Ca-DTPA and Zn-DTPA given intravenously as a single dose of 10 to 1,000 micromol/kg (0.54 – 54 x maximum human dose, MHD). When treated within one hour of internal contamination, Ca-DTPA resulted in about a 10-fold higher rate of elimination of plutonium in the urine as compared to Zn-DTPA. The chelating capacity of Ca-DTPA is greatest immediately and up to approximately 24 hours after internal contamination when the radiocontaminant is still circulating and readily available for chelation. After the first dose of Ca-DTPA, maintenance treatment with either Ca-DTPA or Zn-DTPA resulted in similar rates of elimination of radioactivity. However, at comparable doses, Zn-DTPA had less toxicity (e.g., less depletion of trace metals, lower rate of mortality, the absence of kidney and liver vacuolization, and absence of small bowel hemorrhagic lesions).

In another study, rodents contaminated with aerosolized plutonium and americium were treated with Ca-DTPA and Zn-DTPA. The treatment schedule involved inhalation of Ca-DTPA 2 micromol/kg (0.11 MHD) 30 minutes after contamination followed by inhalation of Zn-DTPA 2 micromol/kg at approximately 6 hours, 1, 2, 3, and 6 days, then twice weekly to day 26 or day 27. The treatment regime reduced the lung deposit of plutonium and americium to 1 - 2% of that in untreated animals. Systemic deposit in liver and skeleton were reduced by half.

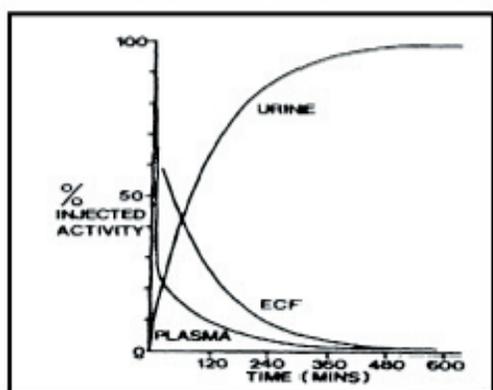
Literature and U.S. Registry data in humans indicate that intravenous administration of Zn-DTPA forms chelates with radioactive contaminants found in the circulation, interstitial fluid, and tissues. When Zn-DTPA is administered by inhalation, it can chelate transuranium elements. Expectoration is expected to decrease the amount of radioactive contaminant available for systemic absorption.

The effectiveness of chelation decreases with time after internal contamination because the transuranium elements become incorporated into the tissues. Give chelation treatment as soon as possible after known or suspected internal contamination with transuranium elements has occurred. [See *Dosage and Administration* (2.1, 2.2)]

12.3 Pharmacokinetics

Plasma retention and urinary excretion data were obtained in 2 subjects that received 750 kBq of ^{14}C -DTPA. As shown in Figure 1, the radiolabeled DTPA was rapidly distributed throughout the extracellular fluid space and was cleared by glomerular filtration. The plasma retention up to 7 hours post dosing was expressed by the sum of three exponential components with average half-lives of 1.4 min, 14.5 min, and 94.4 min. The level of activity in the plasma was below the limit of detection 24 hours after injection. During the study, no detectable activity was exhaled or excreted in the feces. By 24 hours, cumulative urinary excretion was more than 99% of the injected dose.

Figure 1: Percent of ^{14}C -DTPA Distribution



Absorption

Zn-DTPA is poorly absorbed in the gastrointestinal tract. In animal studies, after oral administration, absorption was approximately 5%. In a U.S. Registry of 18 patients who received a single inhaled or intravenous dose of 1 gram, urine data indicate that the inhaled product was absorbed and resulted in a comparable elimination of the radiocontaminant. One study of 2 human subjects that received Ca-DTPA with ^{14}C -DTPA by inhalation revealed approximately 20% absorption from the lungs. Human or animal bioavailability comparisons for Zn-DTPA are not available after administration by inhalation and intravenous injection. [See *Clinical Studies* (14)]

Distribution

Following intravenous administration, Zn-DTPA is rapidly distributed throughout the extracellular fluid space. No significant amount of Zn-DTPA penetrates into erythrocytes or other cells. No accumulation of Zn-DTPA in specific organs has been observed. There is little or no binding of the chelating agent by the renal parenchyma.

Metabolism

Zn-DTPA undergoes a minimal amount of metabolic change in the body.

Adverse Metabolic Effects

Zn-DTPA results in minimal depletion of magnesium and manganese.

Elimination

Zn-DTPA is cleared from the plasma in the first few hours after dosing through urinary excretion by glomerular filtration. Renal tubular excretion has not been documented. In stool samples, only a very small amount of radioactivity (<3%) was detected.

Renal Impaired and/or Compromised Liver Function Patients

Adequate and well-controlled pharmacokinetic and pharmacodynamic studies in renally impaired and/or hepatically impaired patients were not identified in the literature. Both Zn-DTPA and its radioactive chelates are excreted by glomerular filtration. Impaired renal function may decrease their rates of elimination and increase the serum half-life of Zn-DTPA.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies with Zn-DTPA to evaluate carcinogenesis, mutagenesis and impairment of fertility have not been performed. Data for Zn-DTPA effects on spermatogenesis are not available.

13.2 Animal Toxicology and/or Pharmacology

[See *Clinical Pharmacology* (12)]

14 CLINICAL STUDIES

All clinical data has come from the treatment of individuals who were accidentally contaminated. Observational data were maintained in a U.S. Registry of individuals with internal radiation contamination primarily from acute occupational contamination with plutonium, americium and curium.

In 286 individuals, bioassays were available to measure urinary radioactivity elimination after chelation therapy. Of these 286 individuals, 18 had matched pre- and post-chelator urine radioactivity bioassay results available. The majority of these individuals received Ca-DTPA as the initial component to their chelation therapy. When multiple chelator doses were administered over days, the standard of practice was to switch therapy to Zn-DTPA following an initial dose of Ca-DTPA. Although both chelators were considered equipotent 24 hours following internal contamination, Zn-DTPA was considered less toxic. In one individual who received 3 doses, 1 gram each, by nebulization (1:1 Zn-DTPA and saline) followed by 6 intravenous doses, the urinary excretion of plutonium after the first nebulized dose was increased by a factor of 45.

After initial treatment with Ca-DTPA, maintenance treatment was continued with daily 1 gram Zn-DTPA doses administered over a period of days, months or years, depending on the extent of internal contamination and individual response to therapy. Treatment was generally continued until the excretion enhancement factor (EEF) approached 1. The longest treatment duration was 3.5 years. Similar increases in urinary radioactivity elimination were supported by data from the remaining 268 individuals in the U.S. Registry and from the literature.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

Zn-DTPA is supplied as a sterile solution in 5 mL single-use clear glass ampoules at a concentration of 200 mg/mL for intravenous use. Each ampoule contains the equivalent of 1000 mg of pentetate zinc trisodium.

NDC 52919-002-03: 5 mL single-use ampoules, package of 10

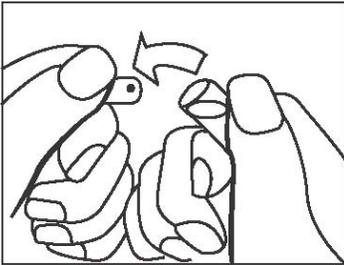
16.2 Storage

Store between 15 - 30°C (59 - 86°F).

16.3 Handling

Inspect parenteral drug products visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The product may be filtered using a sterile filter if particles are seen subsequent to opening of the ampoule.

OPC ampoule: to open, turn so that the point faces upward and break off the neck with a downward movement.



17 PATIENT COUNSELING INFORMATION

Instruct patients to:

- drink plenty of fluids and void frequently to promote dilution of the radioactive chelate in the urine and minimize radiation exposure directly to the bladder.
- use a toilet instead of a urinal, and flush several times after each use.
- clean up spilled urine or feces completely and wash hands thoroughly. Wash clothing or linens separately if blood or urine comes in contact.
- dispose of any expectorant carefully. Avoid swallowing the expectorant if possible.

Instruct parents and child-care givers to take extra precaution in handling the urine, feces, and expectorants of children to avoid any additional exposure to either the care-giver or to the child.

Instruct nursing mothers to take extra precaution in disposing of breast milk. [See *Use in Specific Populations* (8.3)]

18 COLLECTION OF PATIENT TREATMENT DATA

To develop long-term response data and information on the risk of developing late malignancy, detailed information on patient treatment should be provided to the manufacturer (see Patient Treatment Data Form). To obtain additional forms, please use the enclosed form as a template or see the following website:

www.zn-dtpa.com. These data should include a record of the radioactive body burden and bioassay results at defined time intervals, a description of measurement methods to facilitate analysis of data, and adverse events.

Questions regarding the use of Zn-DTPA for the treatment of internal contamination with transuranium elements may be referred to:

hameln pharmaceuticals ltd
Nexus
Gloucester Business Park
Gloucester, GL3 4AG

Tel: + 44 / 1452 / 621661
Fax: +44 / 1452 / 632732
e-mail: drugsafety@hameln.co.uk
United Kingdom

Contact person: Richard Wysocki
Phone : +44 / 1452 / 621661
Fax: +44 / 1452 / 632732
Email: r.wysocki@hameln.co.uk

Revised: 3/2013

Zn-DTPA
Patient Treatment Data

Send to: hameln pharmaceuticals ltd, Nexus, Gloucester Business Park, Gloucester, GL3 4AG, United Kingdom

Date of report: _____	Unique patient identifier: _____
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Patient ID

Name: _____ Date of birth: _____ Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female
Address: _____
Phone: (_____) _____ Hospitalization: <input type="checkbox"/> No <input type="checkbox"/> Yes Where? _____

Criteria for Diagnosis

Date/time of exposure: _____
Geographic location/details of exposure: _____
<input type="checkbox"/> Lab/field confirmed exposure; method: _____
<input type="checkbox"/> Symptoms of Acute Radiation Syndrome: _____

Contamination

Transuranium element(s): <input type="checkbox"/> confirmed <input type="checkbox"/> suspected; list element(s): _____
Route (check all that apply): <input type="checkbox"/> Skin <input type="checkbox"/> Inhalation <input type="checkbox"/> Wound <input type="checkbox"/> Burn <input type="checkbox"/> Ingestion
Anatomic area affected: _____
Initial radioactivity measurement: _____
How measured: _____

Decontamination

External: <input type="checkbox"/> Skin washed with: _____
<input type="checkbox"/> Wound excised/washed: _____
<input type="checkbox"/> Contraindications to aerosolized treatment (h/o lung disease, cough, dyspnea, chest tightness, wheezing)? _____
Internal:
<input type="checkbox"/> Zn-DTPA Date/time of initial dose: _____/_____/_____ Amount: _____ Total doses: _____ Route: _____
<input type="checkbox"/> Ca-DTPA Date/time of initial dose: _____/_____/_____ Amount: _____ Total doses: _____ Route: _____

Adverse Reaction to Treatment

Adverse Reaction(s) to treatment? <input type="checkbox"/> No <input type="checkbox"/> Yes; provide details: _____
Vital signs: Baseline <input type="checkbox"/> Stable <input type="checkbox"/> Unstable: _____
Subsequent (if abnormal): _____
Disposition of patient/outcome of treatment: _____

Treatment Team Data

Report completed by: _____ Title: _____
Organization/affiliation: _____
Phone: (_____) _____ Email: _____ @ _____

Comments

Attach Copy of Emergency Records to this Form